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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/547,336

09/01/2005

Kalman Bolla

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3109

466

7590

05/27/2009

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EXAMINER

JACKSON, BRANDON LEE

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/547,336	Applicant(s) BOLLA, KALMAN	
	Examiner BRANDON JACKSON	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-25, 28-31 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-25, 28-31, and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to amendments/arguments filed 5/19/2009. Currently, claims 15-25, 28-31, and 39-41 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/19/2009 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 15-25, 28-31, and 39-41 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-19, 21-22, 28, 32-35, 41 rejected under 35 U.S.C. 103(a) as being unpatentable over Groiso (US Patent Re. 34,753) in view of Shippert (US Patent 4,213,452). Groiso discloses an immobilization device (1) comprising a flat single-piece splint element (2) arranged to cover a fractured portion of a rib, as well as, surrounding non-fractured ribs (fig. 4) an area of skin overlying the rib. The device (1) is made of a plastically deformable plastic (col. 3, lines 18-21). The device (1) comprises an inner and outer face, wherein the inner face is the skin contacted face and the outer face is the face opposite side that faces away from the user. The splint element (1) defines a first layer that is rigid (col. 4, lines 24-27) and formable (col. 3, lines 18-21). The device (1) further comprises a covering (2B), which is a pad that is analogous to tissue. The splint element (2) may be provided with holes (2A). The device (1) inherently may be fitted over the at least one rib and one neighboring rib without any additional aid or tool because when the device is being fitted to the patient, all one is doing is ensuring it is the right size; it is not necessarily being attached or adhered to the user at that time. Groiso fails to disclose the device comprises a layer of adhesive and the device comprising aluminum. However, Groiso does disclose it is known in the art to use

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adhesive to hold the splint in place while it cools and returns to its rigid state (col. 1, lines 41-43). Moreover, Shippert teaches a splint comprising an adhesive layer (10) and a splint (18, 30) bonded to the adhesive layer. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Groiso device to have a layer of adhesive, as taught by Shippert, in order to assist in securing the plate in position and remaining in position so the splint plate does not rotate around the body of the user causing it to be misaligned with the fracture/break.

With respect to claims 18-19, it would have been obvious to one having ordinary skill in the art to use either material because it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Therefore, it would have been an obvious matter of design choice to use plastic or metal, including aluminum, in the device of Groiso for making the most comfortable splint device. Moreover, it is well known in the art for splints to be made of metals, like aluminum. See Bolla et al. (US Patent 6,039,706) on Column 1, Lines 17-20 for evidence of the state of the art the well known use of aluminum splints.

Claims 20, 23, 29-30, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groiso/Shippert, as applied to claims 15-16 and 18-19 above, and further in view of Bolla et al. (US Patent 6,039,706). Groiso/Shippert substantially disclose the invention as claimed; see rejection to claims 15, 18, and 19 above; but does not expressly state that the plastically deformable metal plate is corrugated. Bolla et al. teaches the use of sheet metal (2) being corrugated (42) in a splint device. Bolla

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et al. further discloses that the sheet metal is easily shaped yet permits immobilization (col. 1, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use the plastically deformable metal with corrugations as taught by Bolla et al. in the device of Groiso/Shippert for the purpose allowing the splint to adapt to local irregularities in the extremities or body parts (col. 2, lines 5-13).

The above combination teaches the use of a foil (aluminum/metal sheet) in the splint device. The limitation that it is used for protecting covering of the upper side of the splint element is an intended use limitation.

Groiso/Shippert substantially discloses the invention as claimed, but does not expressly state that the plastically deformable metal plate is corrugated. Bolla et al. teaches the use of sheet metal (2) being corrugated (42) in a splint device. Bolla et al. further discloses that the sheet metal is easily shaped yet permits immobilization (col. 1, lines 20-25). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use the plastically deformable metal with corrugations as taught by Bolla et al. in the device of Groiso/Shippert for the purpose allowing the splint to adapt to local irregularities in the extremities or body parts (col. 2, lines 5-13).

Groiso/Shippert substantially discloses the invention as claimed, but does not expressly state that the adhesive layer is provided with the analgesic agent but it would have been obvious to one having ordinary skill in the art at the time of the invention to have the agent be on the adhesive layer so that it can contact the patient and increase pain relief (col. 5, lines 21-25). Groiso/Shippert does not expressly state the use of a

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protective foil. Bolla et al. teaches the use of a foil (aluminum/metal sheet) in the splint device and further disclose that the sheet metal is easily shaped yet permits immobilization (col. 1, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use the plastically deformable metal with corrugations as taught by Bolla et al. in the device of Groiso/Shippert for the purpose allowing the splint to adapt to local irregularities in the extremities or body parts (col. 2, lines 5-13).

Claims 24 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groiso/Shippert/Bolla as applied to claim 23 above, and further in view of Singh et al (US Patent 6,716,186). Groiso/Shippert/Bolla fail to disclose the protecting foil over the splint is larger than the splint element so as to form a surround rim and being provided with an adhesive layer. However, Singh teaches a splint (11) comprising a protective foil (150) that is larger than the splint element (120) and provided with an adhesive layer (152). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Groiso/Shippert/Bolla device with the configuration of the protecting foil and adhesive, as taught by Singh, in order to prevent movement of the splint element and to secure the protecting foil to the splint and the user.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goiso/Shippert/Bolla/Singh as applied to claim 24 above, and further in view of Nagai et al. (US Patent 4,390,520). Goiso/Shippert/Bolla/Singh fails to disclose the second layer comprises and analgesic. However, Nagai teaches an adhesive containing an

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analgesic agent (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the adhesive layer of Groiso/Shippert/Bolla/Singh, as taught by Nagai, in order to assist in the healing of the injured portion of the body.

Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groiso/Shippert as applied to claim 32 above, and further in view of Nagai et al. (US Patent 4,390,520). Groiso/Shippert substantially discloses the claimed invention; see rejection to claim 32 above. Groiso/Shippert fails to disclose the adhesive layer of device contains an analgesic agent. However, Nagai teaches an adhesive containing an analgesic agent (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the adhesive layer of Groiso/Shippert, as taught by Nagai, in order to assist in the healing of the injured portion of the body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/

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Examiner, Art Unit 3772

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/Michael Brown/
Primary Examiner, Art Unit 3772